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A study to find the optimal dose for vitamin K supplementation in patients being treated with vitamin K antagonists to create an anti-coagulation effect

Submission date 17/03/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 31/03/2008	**Overall study status** Completed	
Last Edited 23/10/2020	**Condition category** Haematological Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
P07.243

Study information

Scientific Title
A study to find the optimal dose for vitamin K supplementation in patients being treated with vitamin K antagonists to create an anti-coagulation effect

Acronym
VIKS-2A

Study objectives
The anti-coagulation treatment with vitamin K antagonists will be more stable and safer with the supplementation of a low daily dose of vitamin K.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Medical Ethics Committee of Leiden University Medical Center on the 4th March 2008.

Primary study design
Interventional

Study design
Randomised double-blind placebo-controlled single-centre trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anti-coagulant treatment

Interventions
The participants will be randomly allocated to the following four groups in equal numbers:
Group 1: 100 µg vitamin K1 (oral), 1 capsule per day (1 dd)
Group 2: 150 µg vitamin K1 (oral), 1 dd
Group 3: 200 µg vitamin K1 (oral), 1 dd
Control group: placebo (oral), 1 dd

The duration of the treatment is flexible, as is the inclusion period. Follow-up will take place six months after the closure of the inclusion period. This means the first patients will receive vitamin K or placebo for six months and the time the inclusion will take. The last patients will only receive vitamin K or placebo for six months.

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Vitamin K supplementation

Primary outcome(s)
Quality of anti-coagulant treatment expressed as time in therapeutic range. Duration of follow-up: until six months after the closure of the inclusion period.

Key secondary outcome(s)
Number of INRs in therapeutic range. Duration of follow-up: until six months after the closure of the inclusion period.

Completion date
31/03/2009

Eligibility

Key inclusion criteria
1. Start treatment with vitamin K antagonists less then four weeks before inclusion
2. Treatment with vitamin K antagonists for a minimal period of six months, with the therapeutic range of International normalised ratio (INR) between 2.5 anf 3.5
3. Aged between 18 and 85 years, either sex
4. Measurement of the INR by the Thrombosis Service Leiden
5. Informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
85 Years

Sex
All

Total final enrolment
400

Key exclusion criteria
1. Treatment for liver failure
2. Dialysis, both peritoneal and haemodialysys
3. Pregnancy, or wish to get pregnant; lactational period
4. Known to have a chronic condition with a life expectancy of less than six months
5. An expected interruption of treatment with oral anti-coagulants for one week or longer
6. Participation in the self-management protocol

Date of first enrolment
01/04/2008

Date of final enrolment
31/03/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Center
Leiden
Netherlands
2300 RC

Sponsor information

Organisation
Netherlands Heart Foundation (Nederlandse Hartstichting) (The Netherlands)

ROR
https://ror.org/05nxhgm70

Funder(s)

Funder type
Charity

Funder Name
Netherlands Heart Foundation (Nederlandse Hartstichting) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2011	23/10/2020	Yes	No